

REMARKS

Status of the Claims

Claims 10, 12-14 and 22-28 are now pending in this application. Claim 10 is independent. Claims 1-9, 11, 15-21 and 29-30 are canceled, and claims 10, 12, 14, 22-23 and 25 are herein amended. Support for the amendments to the claims can at least be found at page 3, lines 8-13 of the specification as filed. Support for the amendment to claim 10 can at least be found in original claim 11; original claim 21; and page 9, lines 1-14 of the specification as filed. No new matter is added. Thus, reconsideration of this application, as amended, is respectfully requested.

Rejection under 35 U.S.C. § 112, Second Paragraph

Claims 10-14 and 21-30 stand rejected under 35 U.S.C. § 112, second paragraph. This rejection is respectfully traversed.

The Examiner has set forth certain instances wherein the claim language is not clearly understood.

In response, Applicants claim 10 is herein amended and recites, *inter alia*, “(a) bringing a test sample into contact with an agent that inhibits a decrease in measured values, wherein said decrease is caused by an interfering substance(s) present in the test sample; and (b) subjecting the test sample to an antigen-antibody reaction with sensitized particles or with an anti-serum.” Support for the added limitation can at least be found at page 9, lines 1-14 of the specification as filed. As indicated, amended claim 10 further defines the immunoagglutination immunoassay. Applicants respectfully submit that the claims, as amended, particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

With regard to dependent claims 12-14 and 22-28, Applicants submit that claims 12-14 and 22-28 depend, either directly or indirectly, from independent claim 10 which is allowable for the reasons set forth above, and therefore claims 12-14 and 22-28 are allowable based on their dependence from claim 10. Thus, reconsideration and allowance thereof are respectfully requested.

While not conceding the appropriateness of the Examiner’s rejection, but merely to advance prosecution of the instant application, Applicants respectfully submit that claims 11, 21

and 29-30 have been canceled, thus rendering this rejection under 35 U.S.C. § 112, second paragraph moot. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

Rejection under 35 U.S.C. § 102(b)

Claim 10 stands rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Moghaddam et al. '718, U.S. Patent No. 5,972,718, ("Moghaddam"). This rejection is respectfully traversed.

According to the Examiner, this rejection is being maintained for the reasons stated on page 2, paragraph 3 of the Advisory Action. Specifically, the Examiner refers Applicants to the disclosure at col. 11, lines 48-56 of Moghaddam '718, which appears to disclose red blood cells or other particles *coated* with antibodies. Thus, the Examiner insists that Moghaddam '718 discloses a species that anticipates the claimed genus.

While not conceding the appropriateness of the Examiner's rejection, but merely to advance prosecution of the instant application, Applicants respectfully submit that independent claim 10 is herein amended to include the limitations of claims 11 and 21. The Examiner indicated in the Advisory Action that claims 11 and 21 have overcome the anticipation rejection by Moghaddam in view of the Applicants arguments submitted on December 23, 2011 (*See* Advisory Action, page 2, paragraph 2). Therefore, Applicants submit that independent claim 10 is also not anticipated by Moghaddam because the subject matter of claims 11 and 21 are introduced into claim 10. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

Rejections under 35 U.S.C. §103(a)

Claims 10-14 and 21-30 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Mitsuhiro et al., JP 09-304384, ("Mitsuhiro") in view of Wada et al., WO 2004/092733, ("Wada") or Senn et al., WO 91/10747, ("Senn") each taken separately. This rejection is respectfully traversed.

A complete discussion of the Examiner's rejection is set forth in the Office Action, and is not being repeated here.

While not conceding the appropriateness of the Examiner's rejection, but merely to advance prosecution of the instant application, Applicants respectfully submit that claims 11, 21 and 29-30 have been canceled, thus rendering this rejection under 35 U.S.C. § 103(a) moot. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

Legal Standard for Determining Prima Facie Obviousness

MPEP 2141 sets forth the guidelines in determining obviousness. First, the Examiner has to take into account the factual inquiries set forth in *Graham v. John Deere*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966), which has provided the controlling framework for an obviousness analysis. The four *Graham* factors are:

- (a) determining the scope and content of the prior art;
- (b) ascertaining the differences between the prior art and the claims in issue;
- (c) resolving the level of ordinary skill in the pertinent art; and
- (d) evaluating any evidence of secondary considerations.

Graham v. John Deere, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966).

Second, the Examiner has to provide some rationale for determining obviousness. MPEP 2143 sets forth some rationales that were established in the recent decision of *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007).

As the MPEP directs, all claim limitations must be considered in view of the cited prior art in order to establish a *prima facie* case of obviousness. See MPEP 2143.03.

Present Invention

The present invention relates to an agent for inhibiting a decrease in measured values in immunoassays, which decrease is caused by an interfering substance(s), as well as an immunoassay using the same. Applicants submit that amended claim 10 describes an immunoassay involving the following steps: "(a) bringing a test sample into contact with an agent that inhibits a decrease in measured values, wherein said decrease is caused by an interfering substance(s) present in the test sample; and (b) subjecting the test sample to an antigen-antibody reaction with sensitized particles or with an anti-serum." As indicated, Applicants have introduced sequential step language in independent claim 10. Applicants note that the specification describes advantages of the steps of the claimed immunoagglutination

method, such as “ease of handling and of the stability of the reagent” (See, page 9, lines 23-26 of the specification as filed). Applicants respectfully submit that this combination of method steps as set forth in independent claim 10 is not disclosed or suggested by Moghaddam.

Distinctions over the Cited References

Mitsuhiro teaches a conjugated diene (co)polymer having sulfonic acid groups and/or sulfonic acid salt groups. Mitsuhiro further teaches that using a conjugated diene (co)polymer, such as 1,3-butadiene, is indispensable.

In contrast, the present invention does not use a conjugated diene (co)polymer. Further, although Mitsuhiro mentions immunoagglutination (only one word), the effectiveness of using the conjugated diene (co)polymer is described only for immunochromatography. Still further, the effectiveness of using the conjugated diene (co)polymer, even for immunochromatography, is not experimentally shown.

Applicants further submit that Wada relates to a migration shift assay. Wada teaches how to carry out a step of contacting a sample with an affinity molecule to form a complex in the presence of a charged polymer. Following the method of Wada, the formed complex is separated after the step of contacting the sample with the affinity molecule. Thus, following the method of Wada, a separation step is indispensable.

However, Wada does not disclose or suggest an immunoagglutination method. In contrast, the present invention, as amended, is directed to an immunoagglutination method that has no separation step. Although Wada refers to the use of polystyrene latex, the polystyrene latex of Wada is used as a charged carrier molecule. As such, Wada is totally silent about the use of polystyrene latex in an immunoagglutination method.

In addition, Applicants submit that while Senn teaches an immunoassay, Senn is also totally silent about an agglutination immunoassay. Specifically, Senn teaches that the non-specific binding between an HIV envelope protein and cell receptors (CD4) can be decreased by an inhibitor between the HIV envelope protein and CD4. Senn further states that a number of sulfonated polyanions were tested for the ability to inhibit the binding with an anti-CD4 monoclonal antibody.

However, Senn merely mentions a polyanion-binding site, which is closely related to, but is different from the binding region of the HIV envelope protein (gp120). As such, the inhibition

of the interaction between HIV envelope protein and CD4 is not disclosed at all. Moreover, even assuming *arguendo* that Senn discloses the inhibition of the binding between CD4 and the HIV envelope protein by the sulfonated polyanion, since CD4 is expressed on the cell surface and CD4 is thought not to exist in the blood serum from which the cells have been removed, there is no experimental data from Senn which shows that the sulfonated polyanion is effective in the detection of an antibody in the blood serum. Therefore, Applicants submit that Senn does not suggest the problem of a decrease in the measured values determined by the latex agglutination method.

In view of the above discussion, Applicants submit that the Examiner has failed to establish that the cited prior art documents would convey to one of skill in the art a reasonable expectation of success to obtain the presently claimed invention. Accordingly, the combination of the cited references does not render the present invention *prima facie* obvious. Thus, Applicants respectfully request reconsideration and withdrawal of this rejection.

With regard to dependent claims 12-14 and 22-28, Applicants submit that claims 12-14 and 22-28 depend, either directly or indirectly, from independent claim 10 which is allowable for the reasons set forth above, and therefore claims 12-14 and 22-28 are allowable based on their dependence from claim 10. Thus, reconsideration and allowance thereof are respectfully requested.

Conclusion

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office Action, and as such, the present application is in condition for allowance.

In view of the above amendment, Applicants believe the pending application is in condition for allowance.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Shawn A. Hamidinia, PhD, Registration No. 58,931, at the telephone number of the undersigned below to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Director is hereby authorized in this, concurrent, and future replies to charge any fees required during the pendency of the above-identified application or credit any overpayment to Deposit Account No. 02-2448.

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Respectfully submitted,

By 

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